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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/527,558 03/16/00 PFIRRMANN

R 1194-153

EXAMINER

HM12/0919

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MATERIAL

ART UNIT

PAPER NUMBER

1623

10

DATE MAILED:

09/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/527,558

Applicant(s)

Pfarrmann

Examiner

Leigh Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 5, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 21-23 is/are pending in the application.
- 4a) Of the above, claim(s) 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4, 5
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Status of the Claims

Claims 16-20 have been canceled. Claim 1 has been amended. Claims 21-23 have been added. Claims 1-15 and 21-23 are pending. Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Newly submitted claims 21-23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally presented claims are directed to a method of preventing thrombosis formation, and the new claims are directed to a liquid-delivery system.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 U.S.C. § 103

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over LEHNER (WO 98/28027) and REINMULLER (US 5,077,281).

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The invention is drawn to a method of preventing thrombosis formation on a liquid-containing surface of a liquid-delivery system comprising a regimen of either:

- A. Forming a seal in the system containing taurolidine, taurultam, or a mixture thereof and an anticoagulant agent, other than taurolidine or taurultam.
- B. First contacting surface with solution containing an anticoagulant agent other than taurolidine or taurultam and thereafter contacting said surface with a solution containing taurolidine, taurultam, or a mixture thereof and repeating between delivery of liquids.

Both regimens have been amended to designate the inclusion of an anticoagulant agent other than taurolidine, taurultam, or a mixture thereof. Regimen A has been amended to recite "forming a seal" rather than simply contacting the surface.

LEHNER teaches a method of combatting infection or sepsis in a liquid delivery system. The method comprises the use of taurolidine or taurultam for flushing or temporarily sealing said system. LEHNER does not teach the use of these solutions for the prevention of thrombosis formation in said system. LEHNER further does not teach the addition of another anticoagulant agent other than taurolidine, taurultam, or a mixture thereof.

REINMULLER teaches a small genus of taurolin derivatives having bactericidal and coagulation-inhibiting action. This genus includes taurolidine (also known as taurolin) and taurultam, species which are the preferred compounds in the genus. See col 1, lines 40-47 and col 3, lines 27-62. REINMULLER teaches that contact of a solution of taurolin (taurolidine) renders a surface thromboresistant. REINMULLER does not specifically exemplify the use of another

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anticoagulant agent, such as heparin. However, the use of other anticoagulants, such as heparin, is expressly suggested. See col 4, lines 33-40. REINMULLER does not teach sealing a liquid delivery system with a solution containing taurolidine, taurultam, or a mixture thereof and an anticoagulant agent, other than taurolidine or taurultam.

It would have been obvious to one having ordinary skill in the art to have used a solution of taurolidine, taurultam, or a mixture thereof and an anticoagulant agent, such as heparin or coumarin, other than taurolidine or taurultam to prevent thrombosis formation in a liquid-delivery system either by using the solution to flush the system or by sealing the system with the solution. It would be within the scope of the artisan to determine the optimum time for treating the system and the optimum concentrations for the method with routine experimentation.

Claims 1, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over LEHNER (WO 98/28027) and REINMULLER (US 5,077,281) in further view of ITO et al (US 5,167,960).

LEHNER and REINMULLER teach as set forth above. These references do not teach the full range of anticoagulants recited in claim 14. However, as set forth above, REINMULLER does expressly suggest the use of other anticoagulants.

ITO teaches the use of other thrombogenesis inhibitors, such as hirudin, in liquid delivery systems.

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It would have been obvious to one having ordinary skill in the art to have used a solution of taurolidine, taurultam, or a mixture thereof and any art-disclosed anticoagulant agent, other than taurolidine or taurultam to prevent thrombosis formation in a liquid-delivery system either by using the solution to flush the system or sealing the system with the solution. It would be within the scope of the artisan to determine the optimum time for treating the system and the optimum concentrations for the method with routine experimentation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Monday-Friday 7:00 to 3:30 (ET).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Secure and confidential access to patent application status is now available; see <http://www.uspto.gov/ebc/index.html> for more information.

Leigh C. Maier
Patent Examiner
September 17, 2001


Kathleen Kahler Fonda
Primary Examiner
Art Unit 1623